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Food and Drug Administration
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USA

US FDA Bioterrorism Act of 2002: Draft Regulations for Registration of Food Facilities (docket # 02N-0276) and Prior Notice (docket # 02N-0278)

The following are the comments of the members of the Pet Food Association of Canada in response to the issuance on an information document pertaining to the US FDA Bioterrorism Act of 2002. The Pet Food Association of Canada is a trade association representing manufacturers of pet foods sold in Canada, comprising approximately 90% of the pet food tonnage sold here. In addition, our Canadian-based manufactures export their products to many countries worldwide, including the United States of America.

Overview of Registration of Food Facilities and Prior Notice

It is the view of our members that the proposed Regulations for registration of food facilities and prior notice will impede trade between our members and their customers in the United States and make Canadian-made pet foods uncompetitive because of increased costs of administering this program. Much of the required information is a duplication of effort and already a matter of record pursuant to the NAFTA agreement. Moreover, the increased workload: additional documentation for each load; increased contact with agents, carriers, 3rd party logistics company, the FDA and consignee all add to the costs of production, placing the Canadian exporter at a competitive disadvantage. Further the increased effort in shipping product to the United States will result in time delays and in some cases, financial penalties from customers if shipments arrive late.

Facilities Registration

1. As previously noted, much of the registration information is already a matter of record under the NAFTA agreement. While producing registration information isn't of itself problematic, the duplication of effort and extra administrative steps associated with the Bioterrorism Act comes at a cost to Canadian manufacturers.

02N-0276 C70

2. Pursuant to the draft regulations, registrants will be required to update any changes to information previously submitted within 30 days. We would ask for clarification of "changes to information previously submitted." For example, would this apply to temporary plant closures due to weather, fumigation activities, line changeovers, etc. We note that the FDA has the authority to suspend registrations and would suggest that a clear delineation of the circumstances under which a registration might be suspended be sought—we are looking to ensure that this authority extends only under the parameters of the Bioterrorism Act and not for broad authority to impede a company's ability to export its product.

3. It is questionable as to how a US Agent, who will have little information about the manufacturer's operations at best, will in any way reduce the threat of terror to the United States. As controller of production and shipping, the manufacturer is in the best position to provide accurate and timely information on shipments. Allowing the manufacturer to produce its own notices will increase accuracy, timeliness and reduce costs.

4. The cost of retaining a US Agent for is a new cost for many manufacturers. Further the addition of an agent adds a new layer to the communication between manufacturing company, trucking company, FDA and the Agent, thus further slowing down a manufacturer's ability to get the product "out of the door" and increasing the possibility of inaccurate information.

Prior Notice

1. The proposed regulations appear to be patterned after the concept of "just- in-time" inventories, a system widely utilized by manufactures. However, Industry just-in-time systems work because there is always a safety stock available in case a shipment is late. When applied to the draft regulations, a number of problems come to light, including
   - Unforeseen production problems in the plant
   - Weather delays
   - Traffic accidents
   - Border congestion

   Any or all of these (and more) problems could cause a shipment to arrive outside the prescribed window, which we believe to be too narrow for practical purposes. These are not remote problems, they are those frequently encountered by our members when shipping their products. We would ask that the window of opportunity be expanded to allow for contingencies, or alternatively that more flexibility for changes be built in to the proposed Regulations.

2. Loads that arrive outside of parameters set by the prior notification may be held at the border or sent to a secure facility at the direction of the FDA. This type of transit interruption will cause logistical carriers to increase rates or charge on a per incident basis, in any event increasing transportation costs. Further, late shipments may result in financial penalty to the shipper from their customer. All

of these additional costs result in a reduction in the competitiveness of Canadian-made pet foods.

3. After-hours delays cannot be dealt with in the window of notification. A large amount of border truck traffic flows in the early morning/mid-to-late evening to avoid rush-hour traffic in major centers. Unforeseen delays outside of the proposed window leave shippers without opportunity to notify of change.

The Pet Food Association of Canada appreciates the opportunity to comment on how The Bioterrorism Act of 2002 Draft Regulations for Registration of Food Facilities and Prior Notice will affect the pet food business in Canada. If we may provide additional information, please feel free to contact the writer. For a list of our exporting members, please consult www.petfoodexporters.com

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